UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al*,**
Case No. 2:18-cv-01509

EVIDENTIARY MOTIONS ORDER No. 15

Before the Court are Defendants' Motion to Strike New Opinions Proffered by Plaintiffs' Substitute FDA Expert, Michael G. Beatrice, Ph.D. (ECF No. 464) and Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert Michael Beatrice, Ph.D. (ECF No. 467). For the reasons that follow, Defendants' motions are both **GRANTED IN PART AND DENIED IN PART**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs.

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). *Id.* The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. *Id.* at *4. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *2–4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. *Id.* at *13. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. *Id.* The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25.

In June, the Court determined that Dr. Beatrice's deposition would be limited to opinions that were substantially similar to those offered by Dr. Kessler, whom Dr. Beatrice is replacing as an expert witness. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2:18-cv-1320, 2021 WL 2493125, at *3–4 (S.D. Ohio. June 18, 2021). The unique circumstances presented by Dr. Kessler's departure from this case

were beyond Plaintiff's control. Yet even so, the substitution of this expert was necessarily late. Thus, the Court relied on its discretion to limit Dr. Beatrice's testimony along the same lines as a motion to substitute an expert would be considered. *See id.* at *1. This opinion "necessarily address[ed] whether Dr. Beatrice can offer his new opinions at all, *i.e.* in his report as well as during his deposition," though Defendants would need to file a motion to strike to strike those opinions. *Id.* at *4. Defendants filed a motion to strike some of Dr. Beatrice's opinions in his deposition and report, as well as a motion to exclude his expert opinions under *Daubert*. (ECF Nos. 464, 467.) These motions are now ripe for adjudication.

II. Motion to Strike

A party cannot use a witness who was untimely designated "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Even when the substitution of the expert is substantially justified, as here, courts still limit the scope of substitute expert testimony to that of the original expert's testimony. *Kaepplinger v. Michelotti*, No. 17 CV 5847, 2021 WL 2633312, at *6–7 (N.D. Ill. June 25, 2021). In other words, courts limit the opinions and testimony of a substitute expert to those opinions that are "substantially similar to those presented by" the original expert. *U.S. ex rel. Agate Steel, Inc. v. Jaynes Corp.*, No. 2:13-cv-01907, 2015 WL 1546717, at *2 (D. Nev. Apr. 6, 2015). These opinions must also not "be contrary to or . . . inconsistent with" those presented by the original expert. *Shipp v. Arnold*, No. 4:18-cv-4017, 2019 WL 4040597, at *3 (W.D. Ark. Aug. 27, 2019) (quoting *Lincoln Nat'l Life Ins. Co. v. Transamerica Fin. Life Ins. Co.*, Nos. 1:04–CV–396, 1:06–CV–317, 2010 WL 3892860, at *2 (N.D. Ind. Sept. 30, 2010)). A substitute expert is not required to "adopt the prior expert's conclusions verbatim." *Shipp*, 2019 WL 4040597, at *3 (quoting *Lincoln*, 2010

WL 3892860, at *2). Instead, he "should have the opportunity to express his opinions in his own language after reviewing the evidence[.]" *Lincoln*, 2010 WL 3892860, at *2 (quoting *Morel v. Daimler-Chrysler Corp.*, 259 F.R.D. 17, 22 (D.P.R. 2009)). Ultimately, "[t]he purpose of allowing substitution of an expert is to put the movant in the same position it would have been in but for the need to change experts; it is not an opportunity to designate a better expert." *Jaynes Corp.*, 2015 WL 1546717, at *2.

Defendants argue that Dr. Beatrice offers opinions that this Court concluded were not substantially similar to Dr. Kessler's. (ECF No. 464 at PageID #23479.) Plaintiff counters that Dr. Beatrice should be permitted to offer opinions about the Ventralight ST's misbranding, reperitonealization, design control, Material Safety Data Sheets ("MSDS"), 510(k) application, and Instructions For Use ("IFU"). (ECF No. 477 at PageID #24480.) Plaintiff also argues that he should be permitted to present the other opinions Defendants address in the event that Defendants open the door. (*Id.* at PageID #22481.) Each contention is taken in turn.

A. Misbranding & design control

Plaintiff argues that Dr. Beatrice's misbranding opinion, which is that the Ventralight ST's IFU was misleading, and his design control opinions should not be struck. (ECF No. 477 at PageID #24483, 24490.) Because Dr. Kessler opined that the resorption period statement in the Ventralight ST's 30-day resorption statement in the IFU was misleading due to a lack of clinical support, Dr. Beatrice may offer his similar opinion. Because Dr. Beatrice's opinion relies on additional grounds to reach his conclusion, he may offer those opinions as well to explain his primary conclusion that the IFU statement lacked sufficient support.

As an initial matter, no expert may assert that a device is misbranded or misleading under the Food, Drug, and Cosmetic Act and FDA regulations because these are legal conclusions. *Infra*, Part III.C. Dr. Beatrice may opine on the lack of proper clinical support for the 30-day resorption statement in the Ventralight IFU. Additionally, experts may not offer other legal opinions, such as the meaning of the statutory or regulatory scheme surrounding medical devices. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2020 WL 6603657, at *8 (Oct. 20, 2020). Dr. Beatrice may certainly identify the regulations upon which he relies to form his opinions, however.

Dr. Beatrice's opinion about the 30-day resorption statement in the Ventralight IFU is substantially similar to Dr. Kessler's opinions. Like Dr. Kessler, Dr. Beatrice concluded that the 30-day resorption statement lacked sufficient clinical support. (*Compare* ECF No. 477-1 at ¶ 178; *with* ECF No. 477-4 at ¶ 210.) Dr. Beatrice offered additional grounds explaining his opinion. He explained that the lack of support was due in part to design control failures, *i.e.* that Defendants' testing was inadequate and additional testing should have been done. (ECF No. 477-4 at ¶¶ 136–37, 207, 210.) That the Ventralight ST's labeling was thus inadequate is the logical consequence of the unsupported statement in the IFU. (ECF No. 477-4 at ¶ 207.) True, Dr. Kessler did not reference additional testing, labeling adequacy, or design controls in reaching his opinion. But Dr. Beatrice's opinions that the testing Defendants did was inadequate and that additional testing was necessary according to design controls is intricately connected to his opinion that the testing Defendants did failed to support the 30-day resorption claim in the Ventralight ST IFU. It is the other side of the same coin. Moreover, Dr. Beatrice

must be able to explain, at least to some extent, how he reached his conclusion that the testing was inadequate, which is dependent on design controls.[2, 3]

B. Other Ventralight ST IFU opinions

Plaintiff claims that Dr. Beatrice and Dr. Kessler hold substantially similar opinions that the Ventralight ST IFU was misleading in other aspects besides the 30-day resorption period and that the IFU did not adequately warn of other risks, including adhesions. (ECF No. 477 at PageID #24496–97.) Dr. Beatrice may not provide additional opinions that other "specific mesh-related concerns" were not sufficiently warned of in the IFU, including recurrence, bowel obstruction, pain, fistula, etc. (ECF No. 477-4 at ¶¶ 200–04.) Again, no expert may offer legal conclusions. *Supra*, Part II.A. No expert will be permitted to opine on the adequacy of the Ventralight ST's IFU with regard to these injuries because adhesions are the only remaining injury in this case. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *14 (S. D. Ohio Sept. 1, 2020). Dr. Kessler did not offer the affirmative opinion that the IFU was problematic because it did not sufficiently warn of adhesions. Dr. Kessler explained that a hernia patch should "protect against . . . adhesions and those other consequences of mesh attaching to a bowel until that healing period." (ECF No. 477-3 at PageID #25347.) Dr. Kessler offered this

[2] Defendants point to this Court's prior order in which it concluded that all misbranding opinions are new. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *2. Previously, Plaintiff focused on prejudice to Defendants, as opposed to whether opinions were in fact new. *Id.* With the benefit of more thorough briefing, the Court now clarifies that these opinions are appropriate substitute opinions.

[3] Plaintiff notes in the course of his argument here that his expert John Quick has been excluded as an expert (ECF No. 477 at PageID #24491), but the Court did not issue such a broad ruling. The Court only concluded that the opinions Defendants challenged were unreliable; the Court determined that Quick was qualified to offer his opinions and that his opinions were relevant. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 18-md-2846, 18-cv-1509, 2021 WL 2643109, at *3–6 (S.D. Ohio June 28, 2021).

explanation to support why the 30-day resorption period was unsupported. Dr. Beatrice may do the same, and he may note that the lack of information about adhesions contributed to the lack of support for the 30-day statement in the IFU.

At this time, the Court cannot further determine the exact nature of the remaining testimony at issue here, such as that Dr. Beatrice's opinion that the IFU should have more adequately warned of the risk of adhesions. The Court endeavors to keep Dr. Beatrice's opinions limited to those substantially similar to Dr. Kessler, but this does not require a line-by-line determination of whether Dr. Beatrice's opinions and reasoning exactly follows those of Dr. Kessler. These are two separate experts, and thus their opinions cannot be identical. The substantially similar inquiry requires substantial similarity, not perfect similarity, and prohibits opinions that are "contrary to or . . . inconsistent with" those presented by the original expert. *Shipp*, 2019 WL 4040597, at *3.

C. Reperitonealization

Next, Plaintiff addresses Dr. Beatrice's reperitonealization opinion, which he argues is more than a design control opinion and closely connected to Dr. Beatrice's IFU misbranding opinion. (ECF No. 477 at PageID #24488.) Dr. Beatrice may point to additional, similar information in support of his conclusion that the 30-day resorption period in the IFU lacked appropriate suport. Dr. Kessler notes what information Defendants had from communications and clinical studies regarding reperitonealization while explaining that the issues with Ventralight ST's IFU statement about o the 30-day resorption period. (ECF No. 477-1 at ¶¶ 171, 171.5.) The 30-day resorption period and the time needed for reperitonealization to occur go hand in hand because the goal of the resorption period is for it to last long enough for reperitonealization, preventing

adhesions. (ECF No. 477-4 at ¶ 104.) Therefore, Dr. Beatrice may do the same, even if he goes into some greater depth regarding reperitonealization from a design control perspective. (*See id.* at ¶¶ 104, 111, 114–15.) This opinion is substantially similar to the one given by Dr. Kessler.

D. MSDS

Plaintiff turns to Dr. Beatrice's MSDS opinion, arguing that Dr. Beatrice should be permitted to opine that the MSDS presents a safety hazard, that it should have been disclosed in Defendants' submissions to the FDA, and that the end users should have been warned along the lines of the MSDS's Medical Application Caution statement. (ECF No. 477 PageID #24494.) Dr. Beatrice cannot offer his affirmative MSDS opinions.

Dr. Kessler did not provide an affirmative MSDS opinion in his report. Instead, he testified that he disagreed with Dr. Tillman's interpretation of the MSDS, specifically that the end user should have been warned about oxidative degradation of polypropylene as in the MSDS's Medical Application Caution statement. (ECF No. 477-3 at PageID #25033–36.) Dr. Beatrice may do the same, as long as his opinion is not inconsistent with or contrary to Dr. Kessler's opinion. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *2. As stated previously, no expert may testify on the substantive meaning of the MSDS because the MSDS is only admissible as evidence of notice. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-284 6, 2:18-cv-1509, 2021 WL 2643109, at *6 (S.D. Ohio June 28, 2021).

E. 510(k) application

Plaintiff next moves to Dr. Beatrice's 510(k) opinions. Plaintiff addresses two types of opinions—one that the 510(k) process does not verify labeling information and

one that Defendants' 510(k) application was misleading. ECF No. 477 at PageID #24495.) Plaintiff prevails so long as these opinions are not legal conclusions and related to the appropriate substitute opinions of Dr. Beatrice.

Plaintiff argues that Dr. Beatrice should be permitted to testify that a successful 510(k) application, *i.e.* one that results in device clearance, does not necessarily mean that device's labeling is complete or accurate, and that the misleading nature of the 30-day statement in the IFU rendered Defendants' 510(k) application misleading. (ECF No. 477 at PageID #24495.) Dr. Kessler opines that the 510(k) process does not serve as an evaluation of the accuracy and completeness of proposed labeling (ECF No. 464-3 at ¶¶ 97, 109), and so Dr. Beatrice may offer his similar opinion. But again, Dr. Beatrice cannot conclude that the 510(k) process was misleading, though he may opine that the 510(k) process also lacked sufficient support because the IFU statement did. *Supra* Part II.A. And Dr. Beatrice may testify as to the consequences of his opinion that the 30-day statement was unsupported, including that the labeling was inadequate, *supra* Part II.A, and now, that the 510(k) application was unsupported due to the 30-day statement in the IFU.

Dr. Beatrice cannot offer his more general 510(k) opinions or his opinion that Defendants' 510(k) application was inadequate in other respects. (ECF No. 477 at PageID #24495.) Moreover, no expert will be permitted to opine on the legal meaning of 510(k) process. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *8.

F. Other opinions reserved for rebuttals

Finally, Plaintiff argues that the Court should permit Dr. Beatrice to offer certain opinions to rebut Defendants' case, otherwise Plaintiff will be prejudiced. (ECF No. 477

at PageID #24497–98.) Plaintiff contends he will not elicit testimony on these topics. (*Id.*) Depending on the course of trial, Dr. Beatrice may be permitted to offer these opinions in rebuttal. But the Court declines to issue hypothetical rulings. The Court's earlier order addressing Dr. Beatrice's opinions stands for now. *See generally In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *1–4.[4]

III. *Daubert* Motion

Expert testimony, *i.e.* testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the

[4] The parties also dispute whether this is the appropriate time for the Court to consider striking Dr. Beatrice's Ventralex, not Ventralight ST, opinions, and whether there was an agreement between the parties to limit the motion to strike to the Ventralight ST opinions. (*Compare* ECF No. 477 at PageID #24480 n.2 *with* ECF No. 479 at PageID #25707 n.2.) In the absence of a consensus, the previous order's conclusion that Dr. Beatrice's Ventralex opinions are not new opinions remains operative. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *2. Moreover, the Ventralex portion of Dr. Beatrice's deposition has not yet occurred. (ECF No. 464 at PageID #23484 n.3.)

qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); *see also* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (quoting 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the

case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Defendants argue that Dr. Beatrice's opinions are (a) unhelpful to the jury, (b) improper state of mind opinions, (c) inappropriate legal opinions, (d) improper MSDS opinions, (e) that Dr. Beatrice is unqualified to offer his opinions, and (f) that his opinions are unreliable. Defendants also argue (g) that Dr. Beatrice's undisclosed and disclaimed opinions should be excluded. Each contention is again taken in turn.

A. Helpfulness to the jury

First, Defendants contend that Dr. Beatrice's opinions are not helpful to jury because his opinions are not on issues requiring expert testimony. (ECF No. 467 at

PageID #23904.) A history without any expert analysis or other application of the expert's expertise is a factual narrative that "should be presented to the jury directly." *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (explaining that such expert testimony is unhelpful to the jury); *In re Rezulin*, 309 F. Supp 2d. at 551 (noting that "percipient witnesses and documentary evidence" are more appropriate venues to introduce relevant history than expert testimony). For instance, the court in *In re Trasylol* concluded that an expert's summaries of emails between defendants' employees without analysis were inadmissible. 709 F.3d at 1346 & n.30. The opinion did "nothing more than rely on [the defendant's] internal documents to improperly opine on [the defendant's] motive." *Id.* at 1346. Expert testimony that relies on expert knowledge and experience to contextualize, analyze, and interpret historical facts is admissible, however. *In re E.I. Du Pont de Nemours & Co.*, 345 F. Supp. 3d 920, 924, 927 (S.D. Ohio 2015); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2646797, at *7 (S.D. Ohio June 28, 2021).

Here, Dr. Beatrice relies on his "knowledge, skill, experience, training, or education," Fed. R. Evid. 702, to conceptualize, analyze and interpret historical facts to reach his regulatory opinions. For instance, Dr. Beatrice opines that clinical research Defendants had in their possession and relied on was insufficient to support the 30-day resorption claim in the Ventralight ST IFU and that additional testing was necessary. (ECF No. 467-1 at ¶¶ 136–37.) Dr. Beatrice is permitted to explain what facts from communications support his conclusion. (*E.g., id.* at ¶¶ 117, 122, 201.) But no expert, however, may opine on Defendants' state of mind or intent. *Infra* Part III.B.

Defendants also identify portions of Dr. Beatrice's report that addresses internal

communications in relation to the butylhydroxyanisol ("BHA") addition to Sepramesh IP which support his opinion that the Ventralight ST is adulterated. (*Id.* at ¶¶ 138–50.) Dr. Beatrice's opinion in this area has been limited. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *2. To the extent Dr. Beatrice relies on these emails as support for his opinion on adulteration, it is irrelevant and unhelpful to the jury. Yet, to the extent that this complicated medical device communications support Dr. Beatrice's admissible opinions or rebuttal testimony, it would be helpful to the jury.,

Defendants argue that "Dr. Beatrice does not faithfully interpret the facts he recites." (ECF No. 467 at PageID #23905.) These are factual disputes for the jury and these disputes go to the weight of Dr. Beatrice's testimony.

B. State of mind opinions

Defendants next argue that Dr. Beatrice offers inadmissible state-of-mind opinions. (ECF No. 467 at PageID #23906–08.) Plaintiff counters that Dr. Beatrice does not offer impermissible state of mind opinions; Dr. Beatrice opines on what information was available to Defendants as demonstrated by its internal communications. (ECF No. 487 at PageID #25982.) Both sides are partially correct.

Dr. Beatrice clearly opines on Defendants' and the FDA's state of mind. An expert witness cannot opine on an entity's state of mind, including knowledge, motive, and intent. *E.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (concluding that expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh*

Prods. Liab. Litig., Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643114, at *8 (S.D. Ohio June 28, 2021). Dr. Beatrice testified that he will offer an opinion about the intent of the FDA. (ECF No. 467-2 at PageID #24137, p. 44–45.) Dr. Beatrice cannot offer this opinion.

But, as Plaintiff points out, an expert may indicate what information was in Defendants' possession, which oftentimes is referred to synonymously as knowledge. *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 479 (S.D.N.Y. 2016). In various instances, Dr. Beatrice offers opinions like this. For example, he explains that Defendants had certain "knowledge in their possession," which is based on internal communications in which Defendants acknowledged this information. (*E.g.*, ECF No. 467-1 at ¶ 135–36.) And, presuming Dr. Beatrice is otherwise qualified, he can offer an opinion considering this information—as he does. But Dr. Beatrice may not testify that the statement was misleading while noting information available to Defendants, as he also does: "With the above knowledge in their possession . . . this is a misleading statement in labeling[.]" *Id.* This is an impermissible legal opinion. *Infra* Part III.C. Dr. Beatrice's characterization of Defendants' conduct as "misleading and deceptive within the regulatory framework" (ECF No. 464-4 at ¶ 210) is also a commentary on the credibility of other witnesses, *i.e.* Defendants. This is impermissible. "[E]xpert witnesses 'may not testify about the credibility of other witnesses' because '[i]t is the province of the jury to assess the credibility of witnesses." *Babb v. Maryville Anesthesiologists P.C.*, 942 F.3d 308, 316 (6th Cir. 2019) (citation omitted). However, Dr. Beatrice may testify that the 30-day resorption statement in the IFU lacked support. To avoid further issues on this point, Dr. Beatrice should refrain from using words like "knew" or "aware" and should use more

descriptive language, such as possessing information or acknowledging information.

C. Legal Opinions

Defendants next contend that Dr. Beatrice offers inadmissible legal opinions, such as "that the Ventralight ST is adulterated and misbranded, that Bard should have submitted a premarket approval application instead of a 510(k) application, and that the 510(k) application submitted was inadequate. (ECF No. 467 at PageID #23923.) Dr. Beatrice's affirmative opinion related to adulteration is a new opinion, which Dr. Beatrice cannot offer as a substitute witness. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *2. Additionally, no expert, including Dr. Beatrice, may offer legal opinions, such as that the Ventralight ST was "misbranded." *Filing v. Phipps*, 503 F. App'x 297, 300 (6th Cir. 2012). Plaintiff agrees that Dr. Beatrice will not use the terms "misbranded." (ECF No. 487 at PageID #25975.) Plaintiff also represents that Dr. Beatrice will not offer the opinion that Defendants should have sought premarket notification. (*Id.* at PageID #25989.) Thus, there is no reason to address whether this is a legal opinion.

Defendants also argue that Dr. Beatrice's opinion that the 510(k) was inadequate due to the 30-day resorption statement is inappropriate because Dr. Beatrice misinterprets animal studies and because the opinion is preempted. (ECF No. 467 at PageID #23924–25.) Defendants' qualms with Dr. Beatrice's interpretation of a study is does not render it a legal opinion, however. And this Court has already concluded that *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), holds that the [Food, Drug, and Cosmetics Act] preempts claims, not evidence." *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *10.

D. MSDS

Defendants move on to Dr. Beatrice's MSDS opinions, arguing that several types of MSDS opinions are inadmissible. (ECF No. 467 at PageID #23925–26.) Plaintiff contends that Dr. Beatrice will not offer any MSDS opinions "other than for notice purposes." (ECF No. 487 at PageID #25989.) This is an appropriate purpose. Plaintiff does not address any of Dr. Beatrice's MSDS opinions that he addressed in the motion to strike briefing.

The only other argument that Defendants raise with regard to MSDS opinions is that Dr. Beatrice is unqualified to opine on the meaning of the MSDS's Medical Application Caution statement. (ECF No. 467 at 23926.) Because the MSDS is only admissible to show notice, *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *6, there is no need to determine Dr. Beatrice's qualifications to offer an inadmissible substantive opinion about the meaning of the MSDS.

E. Qualifications

Defendants contend that Dr. Beatrice is unqualified to offer three opinions: (1) that Defendants' testing on the ST resorption period did not support the IFU statements and required further testing, (2) that the IFU was inadequate, and (3) that Defendants' 510(k) was inadequate and that Defendants should have sought premarket approval. (ECF No. 467 at PageID # 23909–13.) Some of these opinions have been limited previously, but the Court concludes that Dr. Beatrice is sufficiently qualified to offer his opinions.

Dr. Beatrice is qualified to offer these opinions based on his design control experience. Dr. Beatrice is a regulatory expert, which includes design control and labeling experience. He has over 40 years of experience in FDA regulatory work,

including serving as a consultant on these issues to this day. (ECF No. 467-1 at ¶¶ 1, 4.) Dr. Beatrice worked for the FDA as a regulator, inspector, and reviewer. (*Id.* at ¶10.) Then he spent more than 16 years working in regulatory compliance in high-seniority positions for private companies. (*Id.* at ¶¶ 10–13.)

Defendants argue that Dr. Beatrice is unqualified to offer opinions on the adequacy of clinical studies from a scientific perspective because he has no medical, engineering, or scientific training; experience interpreting studies; or experience with surgical mesh devices. (ECF No. 467 at PageID #23909–11.) As the Court reads the expert report, Dr. Beatrice does not offer opinions on the scientific soundness of the testing. The crux of Dr. Beatrice's affirmative opinion is that if Defendants identified a 30-day resorption period as a design input and listed it in the Ventralight ST's IFU, then testing was necessary for a regulatory perspective to validate the 30-day period. In the absence of such testing, the testing in hand was inadequate and additional testing was necessary to satisfy these regulatory requirements. (ECF No. 464-4 at PageID #96–136.) It appears that this is about matching the claim in the label to the conclusions in clinical studies. Accordingly, Dr. Beatrice is qualified to offer his opinion.

Defendants argue that Dr. Beatrice has no experience interpreting studies and that some of the studies found that even without a 30-day resorption period, sufficient cell growth to prevent adhesions had occurred within 30 days. (ECF No. 467 at PageID #23910–11.) This says nothing of Dr. Beatrice's ability to review the labeling claim that there is a 30-day resorption period and conclude that the studies do not reach this same conclusion as required by the regulations. Defendants only identify their disagreement with Dr. Beatrice's opinion, not anything related to his qualifications. Relatedly,

Defendants contend that Dr. Beatrice's lack of experience with mesh devices renders him unqualified. (ECF No. 467 at PageID #23911.) But the design control and labeling regulations apply to more than just mesh devices, meaning Dr. Beatrice's more general experience with medical labeling is adequate.

Defendants also counter that Dr. Beatrice cannot opine on the adequacy of the resorption statement in Ventralight ST IFU because he has no idea what a foreseeable user of the device would need to see in a warning. (ECF No. 467 at PageID #23912.) This Court has held in this case that experts who are hernia surgeons who have used mesh devices are qualified to opine on the adequacy of a warning from the vantage point of the end user. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *16 (S.D. Ohio Sept. 1, 2020). But this does not mean that only these experts are qualified to offer any opinion about the adequacy of the warning. Dr. Beatrice opines that from a regulatory perspective Defendants' 30-day resorption statement in the IFU is inadequate. (ECF No. 464-4 at ¶ 210.) This is proper, considering Dr. Beatrice's regulatory qualifications.

F. Reliability

Defendants argue that Dr. Beatrice's opinions on the adequacy of Defendants' testing are unreliable, that his design control opinions are based on unreliable methodology, and that he has no scientific basis for his opinions that the Ventralight ST IFU is inadequate in relation to other risks, including adhesions. (ECF No. 467 at PageID #23914–23.) The Court here considers the reliability of Dr. Beatrice's testing and design control opinions with regard to the 30-day resorption statement in the IFU because Dr. Beatrice cannot offer his other opinions. *See supra* Part II.A, D. Defendants' challenges

to Dr. Beatrice's affirmative expert opinions are limited to this area. Dr. Beatrice employs a sufficiently reliable methodology for his affirmative opinions that are not inconsistent with or contrary to Dr. Kessler's opinions and testimony.

As noted previously, the *Daubert* factors, such as scientific methodology, are not dispositive, and "[m]any factors will bear on the inquiry" of reliability. *Daubert*, 509 U.S. at 593. When "[t]he *Daubert* factors do not apply as readily . . . courts must consider other factors when determining admissibility, such as whether the expert has enough education and relevant experience to reach a reliable opinion." *Kovaly v. Wal-Mart Stores Tex., LLC*, 627 F. App'x 288, 291 (5th Cir. 2015) (footnote omitted) (citing *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.,* 388 F.3d 976, 982 (6th Cir.2004)). Courts have considered an expert's regulatory experience and training as sufficient indicators of reliability under these circumstances, including in the FDA regulatory context. *Id.* (pointing to the expert's pharmacy experience and expertise with Texas pharmacy regulations); *Par Pharm., Inc. v. Hospira, Inc.*, No. 17-944-JFB-SRF, 2019 WL 2396748, at *3 (D. Del. June 6, 2019) (holding an FDA regulatory expert's opinion was reliable due to her knowledge and experience). In *Baldonado v. Wyeth*, for example, the district court concluded that an FDA regulatory expert's opinion that additional testing was necessary according to FDA labeling regulations was reliable due to her knowledge of and training on the FDA regulations and her experience advising drug manufacturers on these regulations. No. 04 C 4312, 2012 WL 3234240, at *5 (N.D. Ill. Aug. 6, 2012) (collecting cases). The expert specifically used the methodology that she was trained to use at the FDA. *Id.*

Dr. Beatrice relies on his knowledge and expertise on FDA regulations, rendering

his opinions reliable. He worked for the FDA for twenty-two years as a regulator, inspector, and reviewer; spent 13 years at a multinational corporation as a regulatory and quality compliance officer, and since then has served as a consultant doing the same. (ECF No. 467-1 at ¶¶ 4–15.) Like the expert in *Baldonado*, Dr. Beatrice relies on the methodology he was trained to use at the FDA. (ECF No. 467-2 at pp. 14–15 , 26.) This methodology is evident in Dr. Beatrice's report. First, Dr. Beatrice sets forth the relevant design control and labeling regulations. (ECF No. 467-1 at PageID ¶¶ 54–62, 80.) Then, he applies these regulations to the facts matter at hand. When Dr. Beatrice opines that Defendants' 30-day resorption statement was unsupported because it lacked data and Defendants should have conducted more testing (*Id.* at ¶ 210), he references FDA guidance documents (*id.* at PageID #23972 n.165–67) and draws on regulations that he quoted earlier (*id.* at ¶ 80 (noting that a device does not comply with labeling regulations when it does not include certain types of information).) And to the extent Dr. Beatrice relies on design control opinions to explain why this statement was unsupported, the same holds. Dr. Beatrice points to regulations establishing that design inputs, or what features a device is intended to have, must be validated, or tested. (*Id.* at ¶ 54.) Thus, where Defendants did not have testing confirming that the ST barrier could last 30-days, Dr. Beatrice relied on reliable methodology to reach his conclusion that Defendants failed to satisfy design control regulations. (*Id.* at ¶ 197.)

Dr. Beatrice provides more detail than necessary with regard to the FDA regulations and guidance documents, both of which are essentially legal matters. While he may opine on whether Defendants violated FDA regulations, upon request, the jury will be instructed that violations of such regulations are only of evidence negligence or

misrepresentation. And the regulations themselves do not provide the standard the jury will apply. But the information in his report sufficiently demonstrates the methodology he was following, and more detail can be drawn out on cross-examination. Dr. Beatrice's knowledge and experience with FDA regulatory compliance is robust enough to convey sufficient reliability of his opinions.

Defendants present no persuasive argument to the contrary. First, they contend that Dr. Beatrice does not point to other manufacturers' practices or identify an additional study or test that they could have done to satisfy the regulations. (ECF No. 467 at PageID #23914–15.) There is no discernable basis for requiring Dr. Beatrice's opinions to address these topics. Dr. Beatrice approaches his opinions from a regulatory aspect, so it is sufficient that he identifies applicable regulations and opines that Defendants did not satisfy those regulations based on his knowledge and experience.

Defendants also disagree with Dr. Beatrice's interpretation of their studies and other evidence, and urge that Dr. Beatrice did not sufficiently review the materials upon which he relies, that his FDA training is outdated, and that his reliance on audit documents is inadequate (ECF No. 467 at PageID #23915–19; ECF No. 492 at PageID #26276.) These criticisms go to the credibility of Dr. Beatrice and the weight of his opinions, however, and are properly addressed on cross-examination.

Finally, Defendants contend that "any opinion that [they] committed fraud on the FDA . . . is preempted" while relying on *Buckman*. (ECF No. 467 at PageID #23915.) Again, "*Buckman* holds that the [Food, Drug, and Cosmetics Act] preempts claims, not evidence." *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *10.

G. Undisclosed and disclaimed opinions

Defendants also urge the Court to exclude Dr. Beatrice's undisclosed and disclaimed opinions. (ECF No. 467 at PageID #23927–30.) As for Dr. Beatrice's undisclosed opinions about general causation, the science of reperitonealization, and whether the Ventralight ST should have been recalled (*id.* at PageID #23927), Plaintiff responds that they will not be affirmatively offering those opinions. (ECF No. 487 at PageID #25989). Plaintiff also explains that he will only address the timing of reperitonealization (*id.*), an opinion that Defendants do not challenge (ECF No. 467 at PageID #23928.) Finally, the Court also decline to order an expert not to offer a disclaimed opinion because it is simply an admonishment to follow the law. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605542, at *17; *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2493125, at *4.

IV. Conclusion

For the reasons above, Defendants' motion to strike (ECF No. 464) is **GRANTED IN PART AND DENIED IN PART** and Defendants' motion to exclude the opinions and testimony of Dr. Beatrice (ECF No. 467) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

8/1/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE